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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,195	11/14/2003	Joffre B. Baker	39740-0005A	5745

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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,195	BAKER ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,35-47,51-52 and 56-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31,35-47,51,52 and 56-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 31, 35-39, 51,56-57, and 60 drawn to methods of measuring the expression level of RNA transcripts in EGFR expressing cancer cells, classified in class 435, subclass 6.

II. Claim 40, drawn to a method of treating a patient diagnosed with an EGFR-expressing cancer when the patient's expression level of RNA transcripts is already known, classified in class 514, subclass 1.

III. Claims 41-47 and 58-59, drawn to arrays comprising polynucleotides which hybridize specific genes, classified in class 536, subclass 24.3.

IV. Claim 52, drawn to a kit that can be used for quantitative analysis of the expression level of an RNA transcript, classified in class 422, subclass 61.

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. The method of Invention I is for determining the expression level of certain RNA transcripts in patients who have an EGFR expressing cancer. The method of Invention II is for providing treatment for patients with EGFR

expressing cancer, when their expression levels of certain RNA transcripts are already known.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The product as claimed is an array comprising polynucleotides from several genes. This array can be used for generating nucleic acids or synthesizing proteins.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product. The product as claimed is a test kit that contains an extraction buffer/reagents and a protocol, reverse transcription buffer/reagents and a protocol, and qPCR buffer/reagents and a protocol. This kit can be used to make probes or cDNA sequences from an RNA sample.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. The method of Invention II is for the treatment of patients with EGFR expressing cancers, who already know their expression levels of certain RNA transcripts. The product of Invention III is an array that can be used to determine the expression levels of certain RNA transcripts in patients that have EGFR expressing cancers.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. The method of Invention II is for the treatment of patients with EGFR expressing cancers, who already know their expression levels of certain RNA transcripts. The product of Invention IV is a test kit that contains an extraction buffer/reagents and a protocol, reverse transcription buffer/reagents and a protocol, and qPCR buffer/reagents and a protocol.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. The product of Invention III is an array that comprises polynucleotides that hybridize to several genes. The product of Invention IV is a test kit

that contains an extraction buffer/reagents and a protocol, reverse transcription buffer/reagents and a protocol, and qPCR buffer/reagents and a protocol.

Gene Election Requirement Applicable to Inventions I and II

3. If Applicant elects Invention I, then there is a further restriction requirement with respect to Claim 60. Claim 60 reads on patentably distinct inventions drawn to multiple genes. Each gene consists of a different nucleotide sequence, has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, Bak is chemically, structurally and functionally distinct from KRT17. A search for Bak would not be co-extensive with a search for KRT17. Further, a finding that Bak, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that KRT17 is also novel and unobvious over the prior art. Similarly, a finding that Bak is anticipated or obvious over the prior art would not necessarily extend to a finding that KRT17 is also anticipated or obvious over the prior art.

Accordingly, the genes are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, applicant should elect one additional prognostic transcript or combination of transcripts selected from the list of genes in Claim 60.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-IV require different searches that are not co-extensive. For instance, a literature search for the method of treatment in Invention II is not co-extensive with a literature search for the arrays of Invention III. Additionally, a search for each of the methods of Inventions I and II is not co-extensive with one another. For instance, a keyword / literature search for methods of detecting expression levels of RNA transcripts (Invention I) would not be co-extensive with a keyword / literature search for methods for treating a patient with an EGFR-expressing cancer (Invention II). Further, a finding that, for example, the array of Invention III is anticipated or obvious over the prior art would not necessarily extend to a finding that the methods of Inventions I or II or the kit of Invention IV were also anticipated or obvious over the prior art. Similarly, a finding that the method of Invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of Invention II or the array of Invention III or the kit of Invention IV were also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
December 21, 2005

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER